NIOSH recommends that health care facilities use safer medical devices to protect workers from needlestick and other sharps injuries. Since the passage of the Needlestick Safety and Prevention Act in 2000 and the subsequent revision of the OSHA Bloodborne Pathogen Standard, all health care facilities are required to use safer medical devices.



SHARING LESSONS LEARNED

NIOSH has asked a small number of health care facilities to share their experiences on how they implemented safer medical devices in their settings. These facilities have agreed to describe how each step was accomplished, and also to discuss the barriers they encountered and how they were resolved, and most importantly, lessons learned.

DISCLAIMER: Provision of this report by NIOSH does not constitute endorsement of the views expressed or recommendation for the use of any commercial product, commodity or service mentioned. The opinions and conclusions expressed are those of the authors and not necessarily those of NIOSH. More reports on Safer Medical Device Implementation in Health Care Settings can be found at http://www.cdc.gov/niosh/topics/bbp/safer/

Programs for Selecting and Evaluating Safer Medical Devices

Our hospital is a not for profit corporation. We have served this community for over ninety years. We offer a full range of general acute care, drug rehabilitation and specialized health services. We are licensed for 170 beds; we have an admission rate of approximately six thousand patients per year. Our in-patient dialysis unit provides treatment to four - six patients daily. Our facility performs approximately five thousand surgical procedures yearly. We also deliver services via five off site clinics. We provide additional services to the community through our comprehensive detoxification unit, chemical dependency unit, and HIV (Wellness Center).

Phase 4: Evaluate Safer Medical Devices

Describe the safer medical device(s)

Our team decided to evaluate IV catheters and syringes. We chose three IV catheter devices to assess; we used the following criteria to determine which products to evaluate:

- 1. Product handling and safety features
- 2. Manufacturer's capability to supply adequate free products for the pilot project
- 3. Manufacturer's ability to provide pricing assessments and comparisons.

Department or location in which device was evaluated:

Staff who used the device included doctors, anesthesiologists, nurses, and radiology technicians. During the previous two year period, 80%

of needlesticks in our facility were sustained by nursing personnel. Approximately 75-80 IV catheters are used by our staff nurses daily. Therefore,

the nursing staff was an integral part in the development of the selection plan.

We expected the number of needlestick incidents during the evaluation phase to rise slightly, and then decrease after the initial training period was complete.

Describe the staff training on the device.

The first training session was conducted on site in one of the conference rooms. We felt that the staff would learn better in a dedicated location and timeframe. We knew from past experiences that on-unit instruction was difficult to achieve. We decided to keep the initial session short, and to provide the appropriate follow-up on the nursing units. The product representative coordinated with our Education Department to provide the training. The vendor representative was also asked to provide supporting materials, such as videos and handouts before the device was introduced and used.



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Describe the process used to evaluate the device and timeframe for this process.

We had a meeting to devise a plan and a timetable that would guide us through the evaluation and implementation phase. The procedure would involve both managerial and non-managerial (frontline) workers. The plan also included trial periods for each product that was selected. The trial period was to be from 4 to 6 weeks and then the recommendation phase would begin.

List the criteria and measures used in the device evaluation and how it was collected and analyzed.

An evaluation form was given to the staff members who would be assessing the new product. We had the form printed on bright orange paper, in order for the evaluators to keep it separate from all other forms and papers. Three IV catheter products were to be evaluated. The vendors were asked to present visual instructions and testing stations for each product. We also requested an ample number of samples in order for each evaluator to thoroughly test the design and handling of the product.

The evaluation form for product selection criteria included:

Overall use, handling and size of catheter

Overall ease of use and handling of safety mechanism

Sharpness of needle

Flashback Visualization

Ability to Advance/thread catheter

Ability to keep hands behind needle as it is covered

Does this product meet your particular needs?

Overall, catheter evaluation

We also asked the number of catheters that they used during the trial period, and the amount of training they estimated would be required to use the product.



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Did the evaluation process provide sufficient information to determine the effectiveness of the device and whether to continue its use?

We carefully tracked the evaluators, answering questions and providing help when it was needed. The vendors also offered additional assistance. We requested instruction sheets and training videos to be located at the nurse's stations and in the medical staff library. We did not use the same staff members for each product selection assessment. Many staff members were eager to trial the new devices; some team members received calls from people who wanted to assess the devices.

At the end of each testing period we asked that the forms be returned as soon as possible. At the completion of the evaluation phase on all three products, our efforts were rewarded with an 82% compliance rate. This was accomplished after reminders, memos, e-mails, and at times, we were required to chase individuals through parking lots in order to obtain the forms.

In order to determine whether or not the device was used as planned, we found that surprise technique observation and sharps container checks for activated devices were the best solution. The Infection Control department and the CSR department worked together to do visual checks on sharps containers on the nursing units. In addition, each day the CSR department replaced the filled containers for new ones on the IV trays. They were asked to do a visual check for devices that had not been activated. In order to maintain the highest level of safety they were instructed not to shake or disturb the contents. The ICP also conducted random sharps container surveillance rounds.

The feedback that was obtained from the forms helped us to balance safety and practical considerations before determining which device would be suitable for our institution. After assessing the forms, one angio-catheter product was greatly favored by the nurses. The comments for this product far exceeded the other products. Some of the nurses commented that they liked this device because it appeared to cause less pain for the patient. After the team completed the evaluation process, we recommended this product to Administration and the Purchasing Department.



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Lessons Learned / Advice to similar facilities:

Be sure to involve Administration and Purchasing Departments in all facets of the product selection/evaluation phase. If someone from their department cannot attend a meeting, delegate a team member to schedule a meeting to inform them of the team's activities and conclusions. The angio-catheter that the team had selected was one of the most expensive on the market. When the costs (per catheter) were assessed by the purchasing department, we were notified that this particular product was not going to be chosen. The price was so much higher than other devices, this product was not even going to be considered. We were told to review our data and choose another product. We felt that we had wasted the vendor's time and we knew that we should have spent more time assessing the economic profile, as well as our clinical needs.

Other relevant information about the process or problems encountered.

We identified a problem with the collection of the evaluation forms; we had not designated where the forms would be maintained after they were collected. We did not want the forms to be misplaced, and the vendors were requesting feedback from the forms. We named one team member 'keeper of the evaluation forms'; all forms were sent to this particular person. It was an important part of the process that all of the forms were collected in a timely manner and reviewed by the team. Evaluation forms are such an integral step in the assessment process, it is important to have a system in place for collecting and reviewing.



Materials : Copies of Evaluation Forms



Time: Product assessment - Staff Instruction – e- mails - Evaluation form review



Costs: Pens – Snacks for classroom instruction sessions

STAFF HOURS:

Type of Staff	Hours Spent on Phase 4
Management	25
Administrative	4
Front-Line	75
Total	104